

REMARKS

Claims 1-10 are currently pending in the present application. The claims have been amended in the expectation that the amendments will place this application in condition for allowance. The amendments do not introduce new matter within the meaning of 35 U.S.C. § 132. Accordingly, entry of the amendments is respectfully requested.

1. Objection to the Specification

The Official Action states that the specification is objected to for the following reasons:

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Applicants submit herewith an Abstract of the Disclosure on a separate sheet pursuant to the Examiner's request. Applicants respectfully point out to the Examiner that this Abstract is fully supported by the original specification as filed and adds no new matter to the present application. In particular, page 1, line 18 to page 2, line 5 of the original specification as filed provide specific basis for the Abstract.

2. Rejection of Claims 1, 2, 4, 5, and 7 under 35 U.S.C. § 112, 2d paragraph

The Official Action states that claims 1, 2, 4, 5, and 7 are rejected under 35 U.S.C. § 112, second paragraph for the following reasons:

Claims 1, 2, 4, 5, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the

invention. In claim 1, the preamble appears like a method of use claim; however, the claim does not contain any step limitations. For examination on the merits of this claim, it has been treated as a product claim for the aqueous solution. In claim 2, it is not clear as to whether there are two solutions. The limitation "the anion-containing and the cation-containing solution" in claim 4, the limitation "the anion-containing solution" in claim 5 and the limitation "the cation-containing solution" in claim 7 lack antecedent basis.

Applicants respectfully traverse this rejection. Regarding the §112, second paragraph rejection, caselaw has defined two requirements under the statute: (1) whether the applicant has stated the invention as something elsewhere in the application which would not fall under the scope of the claims; and (2) whether the claims would be communicated with a reasonable degree of particularity and distinctness to a person skilled in the art in light of the content of the disclosure and the teachings of the prior art. MPEP §2171, §2173, and §2173.02.

Applicants thank the Examiner for her suggestions regarding the claims. Applicants have amended claims 1-7 to recite the proper method of use format. Additionally, applicants have amended claim 2 to clarify that the electro-chemically activated aqueous solution contains both an anion-containing and a cation-containing solution. Applicants have also amended claims 4 and 5 to depend from claim 2 instead of claim 1, providing antecedent basis for the limitations "the anion-containing and the cation-containing solution", "the anion-containing solution", and "the cation-containing solution", removing the present grounds for rejection.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of pending claims 1, 2, 4, 5, and 7.

3. Rejection of Claims 1 and 8 under 35 U.S.C. § 102(b)

The Official Action states that claims 1 and 8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hayashi et al.

As the basis of this rejection, the Official Action states:

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi et al. Hayashi et al. disclose an irrigating medium comprising an electro-chemically activated, aqueous saline solution (column 1). Patentable weight is not given to its intended use for irrigating root canals.

Applicants respectfully traverse this rejection. The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Hayashi et al. relates to an electrolyzed strong acid aqueous solution for the treatment of mediastinitis. In particular, Hayashi et al. teach the use of a solution having a pH of 2.7 or lower and an oxidation-reduction potential (ORP) of more than 1,100 mV. See page 41, column 2, fourth paragraph.

According to Hayashi et al., these low pH and high ORP values are necessary because "bacteria can only live in a pH environment between 2 and 11.2 and an ORP between -400 and +840 mV, ESAAS is thought to exhibit its bactericidal effect, in part, by providing the condition that does not allow bacteria to survive."

In contrast, the presently pending claims relate solely to irrigating mediums containing and methods of using an aqueous saline solution having a pH of between 6.75 and 8.5 and which is effective at lower ORP's. Since Hayashi et al. only teach aqueous solutions having a pH of 2.7 or lower and not the claimed range of 6.75 to 8.5, the reference does not teach each and every claim limitation as required by *Verdegaal Bros. v. Union Oil Co. of California* either expressly or inherently. Accordingly, a person of ordinary skill in the art would not have been able to arrive at the presently claimed invention based on the teachings of Hayashi et al.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of pending claims 1 and 8.

4. Rejection of Claims 2-4 under 35 U.S.C. § 103(a)

The Official Action states that claims 2-4 are rejected under 35 U.S.C. § 103(a) as being obvious over Hayashi et al. in view of Malchesky (U.S. Patent No. 5,932,171).

As the basis of this rejection, the Official Action states:

Claims 2-4 are rejected under 35 U.S.C. 103(a) as

being unpatentable over Hayashi et al. in view of Malchesky (5,932,171). Hayashi et al. disclose an aqueous solution that shows the limitations as described above; however, they do not show the solution including anion-containing solution and cation-containing solution. Malchesky teaches an aqueous solution of salt including anion-containing solution and cation-containing solution (column 2 lines 19-41). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aqueous solution of Hayashi et al. to have anion-containing solution and cation-containing solution. One would be motivated to make such a modification to utilize the cation-containing solution for cleansing and the anion-containing solution for antimicrobial rinsing as taught by Malchesky. As to claim 4, it is an obvious matter of choice as to the process by which the solutions are produced, because a product claim is properly met if the final product is shown.

Applicants respectfully traverse this rejection. The references of record do not teach or suggest applicants' inventive subject matter as a whole as recited in the claims. The Examiner has failed to establish a *prima facie* case of obviousness against the presently rejected claims.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18

U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art reference must teach or suggest all the limitations of the claims. *In re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

As stated above, Hayashi et al. teach an electrolyzed strong acid aqueous solution for the treatment of mediastinitis after cardiovascular surgery. In contrast, presently pending claims 2-4 relate to methods for treating root canals. Malchesky does not remedy these deficiencies.

Malchesky teaches an apparatus which is used to sterilize medical instruments and equipment, as well as food processing equipment, pharmaceutical processing equipment, animal cages, and other equipment. A strongly acidic solution is used in this apparatus. Malchesky does not teach or suggest methods of treating the human or animal body generically, or methods of treating a root canal in particular.

In contrast, the present application specifically relates to the use of catholyte in the irrigation of root canals. Catholyte is so used because of its detergent abilities, as well as its characteristic ability to be applied topically as a cytoprotective solution. The catholyte seeks to minimize the adverse impact of an otherwise disruptive and traumatic intervention into the root canal. Accordingly, presently pending claims 2-4 relate solely to methods for treating root canals. Neither reference cited by the Examiner discloses this critical element of the presently claimed invention as required by *In re Wilson*. It would not have been obvious to a person of

ordinary skill in the art to extrapolate this use from the teachings of Hayashi et al. and Malchesky.

In particular, it is well known that medical treatments and medicines are very specific to the diseases being treated. It is not obvious to extend a treatment from one disease to the next. Additionally, it is well known that many materials used as a medicament in one application can often result in the manifestation of unwanted side effects in another application. For example, a person of ordinary skill in the art would know that a medicine used to treat a headache would not obviously also treat an upset stomach. Similarly, a person of ordinary skill in the art would not assume that a medicine used for cardiovascular surgery, such as that taught by Hayashi et al., could be successfully applied as a medication for treating a root canal according to the presently claimed invention.

Root canal treatment is a unique procedure which has its own problems and requirements. Biocompatibility of the medication used is of paramount importance and the sterilization ability of any medicament used is generally of secondary importance. As a result, post-operative problems and secondary complications commonly arise following root-canal treatment procedures which are often attributable to the medicaments used during these procedures.

Since root canal tissue is very delicate, one of ordinary skill in the art would not assume that a highly acidic solution, such as that used for the sterilization of steel implements

according to Malchesky, may be used to treat root canal tissue. Indeed, there is a very high probability that the use of solutions suggested by Hayashi et al. or Malchesky would cause substantial problems in root canal treatment and lead to post-operative complications.

Dentists presently use a solution of hypochlorite bleach (with high alkalinity) in root canal treatment due to a dearth of suitable alternatives. It has also been tried to use glutar aldehyde, hibitine (chlor hexidine), peroxide, and some ammonia compounds as a more suitable and biocompatible replacement for hypochlorite without much success. While it is known in the art that anodic electrolyte solution is acidic and cathodic is alkaline, neither of these solutions per se would be readily compatible with the delicate tissue in the root canal. Accordingly, a person of ordinary skill in the art would not have combined the teachings of Hayashi et al. with those of Malchesky to arrive at the presently claimed invention.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of pending claims 2-4.

5. Rejection of Claims 5-7 under 35 U.S.C. § 103(a)

The Official Action states that claims 5-7 are rejected under 35 U.S.C. § 103(a) as being obvious over Hayashi et al. in view of Komatu et al. (U.S. Patent No. 6,231,878).

As the basis of this rejection, the Official Action states:

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi et al. in view of Komatu et al. (6,231,878). Hayashi et al. disclose an

aqueous solution that shows the limitations as described above; however, they do not show the anion-containing solution produced from 10% aqueous NaCl solution and having high redox potential of up to about +1170 mV. Komatu et al. teach anodic electrolytic solution produced from aqueous NaCl solution and having a high redox potential of at least +1050 mV. It is held to be an obvious matter of choice to one of ordinary skill in the art as to the concentration of the aqueous solution of salt and the value of redox potential. The specific concentration of salt in the water to be treated and specific value of redox potential are not critical to the claimed invention. It is known in the art that anodic electrolytic solution is acidic and has a high redox potential, and cathodic electrolytic solution is alkaline and has a low redox potential. As to claims 6 and 7, it is an obvious matter of choice to one of ordinary skill in the art as to the specific range of pH and redox potential value.

Applicants respectfully traverse this rejection. The references of record do not teach or suggest applicants' inventive subject matter as a whole as recited in the claims. The Examiner has failed to establish a *prima facie* case of obviousness against the presently rejected claims.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18

U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art reference must teach or suggest all the limitations of the claims. *In re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

As stated above, Hayashi et al. teach an electrolyzed strong acid aqueous solution for the treatment of mediastinitis after cardiovascular surgery. In contrast, presently pending claims 5-7 relate to methods for treating root canals. Komatu et al. do not remedy these deficiencies.

Komatu et al. teach an acidic analyte with a pH of less than 2.6 which is obtained by electrolysis of salt tap water used for treating dermatoses in domestic animals. Komatu et al. do not teach or suggest methods of treating a root canal in accordance with the presently claimed invention.

In particular, animal skin, the particular organ being treated according to Komatu et al., is a very strong barrier to germs, chemicals, and medication. In contrast, root canal tissue is very delicate and sensitive. Anatomically and physiologically, there is no correlation between treating a strong barrier such as animal skin and treating a delicate and sensitive tissue such as root canal tissue of a human patient. Accordingly, presently pending claims 5-7 relate solely to methods for treating root canals. Neither reference cited by the Examiner discloses this critical element of the presently claimed invention as required by *In re Wilson*. It would not have been obvious to a person of ordinary skill in the art to extrapolate this use from the teachings of Hayashi et al. and

Komatu et al.

A person of ordinary skill in the art would have no motivation to modify a reference regarding the treatment of skin to arrive at the presently claimed invention regarding the treatment of a root canal. There is no parallel between these two situations for a person of ordinary skill in the art to look towards. In this regard, applicants note that the prior art solutions cited by the Examiner have never been used before in the field of root canal treatment since it is well recognized that application of these solutions to root canal treatment would be dangerous to the patient being so treated.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of pending claims 5-7.

CONCLUSION

Claims 1-10 are currently pending in the present application. Applicants respectfully request the Examiner to reconsider and withdraw the outstanding rejections of claims 1-8 and allow all pending claims 1-10 presented herein.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

MARAIS

Examiner: M. Bumgarner

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For: **IRRIGATING MEDIUM FOR ROOT CANALS**

Appendix A

Please amend the following claims as indicated in the following marked up copy of the claims.

1. (Once Amended) [Use of an aqueous solution in the preparation of an irrigating medium for use in the treatment of] A method for treating root canals, comprising applying an irrigating medium to a root canal, wherein the irrigating medium comprises an [the] aqueous solution being characterized in that it is electro-chemically activated and has a pH of between 6.75 and 8.5 with microcidal as well as dispersing and surfactant properties.

2. (Once Amended) The [use as claimed in] method of claim 1, wherein the electro-chemically activated aqueous solution includes both an aqueous anion-containing and an aqueous cation-containing solution.

3. (Once Amended) The [use as claimed in] method of claim 2, wherein the aqueous anion-containing solution and the aqueous cation-containing solution are prepared by means of electrolysis of an aqueous solution of a salt.

4. (Twice Amended) The [use as claimed in] method of claim [1] 2 wherein the anion-containing and the cation-containing solution are produced by an electro-chemical reactor comprising a through-flow, electro-chemical cell having two co-axial electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into cathodic and anodic chambers.

5. (Twice Amended) The [use as claimed in] method of claim [1] 2 wherein the anion-containing solution is produced from a 10% aqueous NaCl solution, electrolysed to produce activated or excited radical cation and radical anion species, the anion-containing solution having an extremely high redox potential of up to about +1170 mV.

6. (Once Amended) The [use as claimed in] method of claim 5 wherein the anion-containing solution has a pH of about 2-7 and a redox potential of about +1170 mV.

7. (Once Amended) The [use as claimed in] method of claim 5 wherein the cation-containing solution has a pH of up to about 7-13 and a redox potential of about -980 mV.

8. (Once Amended) An irrigating medium for irrigating root canals, the irrigating medium comprising an electro-chemically activated, aqueous saline solution having a pH of between 6.75 and 8.5 with microcidal as well as dispersing and surfactant properties.